Notice of Allowability	Application No.	Applicant(s)	
	10/015,930	HIRSH ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment filed 08/11/04*.

2. ☒ The allowed claim(s) is/are *1 and 3-23*.

3. ☒ The drawings filed on *30 November 2001* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *09/13/04* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrea L. Pabst on 08/11/04.

The application has been amended as follows:

Claim 1, lines 1-2, the phrase "in unit dosage form for both intraoral and oral administration to a patient" has been deleted.

Claim 1, line 5, after the phrase "ingredient capable of intraoral administration", the phrase ", having a molecular weight of less than 350, in a dosage of no more than about 50 mg, wherein the molded triturate tablet comprises an excipient and disintegrates or dissolves within 10 minutes permitting rapid release of the pharmaceutically active ingredient" has been inserted.

Claim 5, line 1, the phrase "claim 2" has been amended to "claim 1".

Claim 6, line 2, the word "may be" has been amended to "is".

Claim 6, line 2, the phrase "may contain" has been amended to "contains".

Claim 14, line 10, the word "compolymerss" has been amended to "copolymers".

Claim 16, line 1, the phrase "The pharmaceutical composition defined in claim 1" has been amended to "A pharmaceutical composition which comprises: (a) an intraorally releasing first portion, in the form of a molded triturate tablet comprising a

therapeutically effective amount of a pharmaceutically active ingredient selected from the group consisting of buprenorphine, phentanyl, or ergotamine in a dosage of no more than about 50 mg,".

Claim 16, line 3, the phrase "capable of intraoral administration" has been deleted.

Claim 16, line 4, after the phrase "during intraoral administration", the phrase "and (b) a second releasing portion located around the first portion as a compressed annular tablet, comprising a therapeutic ingredient capable of oral administration and which is releasable and orally ingestible by the patient after the molded triturate has disintegrated or has dissolved intraorally" has been inserted.

Claim 19, line 5, the phrase "drugs fro neurological disorders" has been deleted.

Claim 19, lines 6-10, the phrase "drugs for treating endocrine disorders, drugs for promoting immunology, drugs for treating osteoarthritis, drugs for treating glaucoma, drugs for treating allergic rhinitis, drugs for treating anemias and other hematological disorders, drugs for treating infectious diseases, drugs for the treatment and symptoms of cancer, drugs for insomnia, " has been deleted.

Claim 20, line 7, after the word "administration", the phrase ", having a molecular weight of less than 350, in a dosage of no more than about 50 mg, wherein the molded triturate tablet comprises an excipient and disintegrates or dissolves within 10 minutes permitting rapid release of the pharmaceutically active ingredient" has been inserted.

Claim 21, line 6, after the word "administration", the phrase ", having a molecular weight of less than 350, in a dosage of no more than about 50 mg, wherein the molded

triturate tablet comprises an excipient and disintegrates or dissolves within 10 minutes permitting rapid release of the pharmaceutically active ingredient" has been inserted.

The following is an examiner's statement of reasons for allowance:

The reason for allowance of the claims is the inclusion of pharmaceutically active ingredient having a molecular weight of less than 350 that dissolves within 10 minutes to permit rapid release of active ingredient. The cited reference does not teach active ingredient having a molecular weight less than 350 that rapidly release active ingredient and therefore provide intraoral absorption. The cited reference teaches drug having a molecular weight above 350 that is slightly soluble in water and therefore, not rapidly released.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Griffin, Lewis et al., Jordan et al., and Sterling Drug, Inc are cited as of interest for the teachings of quick dissolved tablet.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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